K023190

OCT 2 4 2002

510(k) SUMMARY

[As required by 21 CFR 807.87(h)]

Identification of Submitter

Corresponding Official:	Richard S. Demke
Establishment:	Siemens Medical Solutions USA, Inc. Nuclear Medicine Group 2501 North Barrington Road Hoffman Estates, IL 60195
Establishment Registration Number:	1423253 (Owner / Operator Number: 9010023)
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Date of preparation:	

Identification of the Product

Device Proprietary Name:	E.CAM Computer / e.soft Workstation
Classification Name:	Emission computed tomography system per 21 CFR 892. ~~1200~~ 2050
Common Name:	Nuclear Medicine Imaging system
Product code:	90 ~~KQI~~ ~~KPS~~ LLZ
Class:	Class II

Models

E.SOFT A	Acquisition
E.SOFT P	Review & Processing
E.SOFT V	Review
E.SOFT AP	Acquisition, Review & Processing

Identification of Legally Marketed Equivalent Devices

Device	Manufacturer	510(k) Number
E.CAM Computer	Siemens Medical Solutions USA, Inc.	K992731
ICON Computer System	Siemens Medical Solutions USA, Inc.	K903315B
ADAC Pegasys	Phillips Medical Systems	K892358
Hawkeye Option for Dual-Headed Variable Angle Gamma Camera	EL GEMS Ltd./ GE Medical	K991841
ECAT PET SCANNER	CTI PET Systems, Inc.	K002715

Device Description

E.CAM Computer / e.soft Workstation provides primary user interface for acquiring images from the Siemens E.CAM family of nuclear medicine Gamma cameras, as well as a collection of clinical applications for processing and review of images from any nuclear medicine and/or positron emission imaging systems. E.SOFT relies on standard networking and image transfer protocols (TCP/IP and DICOM) for connection to/from other devices, including NM, PET and CT imaging stations, image review/storage (PACS) stations, hardcopy devices, external archive devices and HIS/RIS (Hospital information/Radiological Information Systems).

Description of Change or Modification

E.CAM Computer / e.soft Workstation is to be modified to provide attenuation correction with computed tomography images (CT), improved reconstruction with Flash 3D OSEM modeling, PET quantification activity and HIPAA (patient privacy) support.

Intended Use of Device

E.CAM Computer / e.soft Workstation is a Gamma Camera computer for nuclear medicine used to detect or image the distribution of radionuclides in the body or organ, using the following techniques:

- Planar Imaging
- Whole body imaging
- Tomographic imaging (SPECT) for non positron emitter
- Positron imaging by coincidence
- Positron imaging without coincidence up to 588 keV
- Display and process nuclear medicine, PET and CT images

Device Comparison

Attenuation correction is performed by all SPECT vendors, including e.soft with an emission source. Attenuation correction with computed tomography images (CT) is currently performed by GE Medical Systems (K991841). Most SPECT devices support OSEM Reconstruction. E.soft will provide improved processing with Flash 3D OSEM Reconstruction. Pet quantification activity streamlines the use of PET data by combining new & existing pet related displays & processing the data in a single protocol (or activity). The concerns of patient data security, access & privacy are accomplished by supporting the HIPAA directives.

Summary of Design Control Activities

The risk analysis method used to assess the impact of the modifications was based on a Failure Modes and Effects Analysis (FEMA). This analysis built upon the previous risk analysis and incorporated the software modifications indicated in this submission.

Substantial Equivalence

The modified E.CAM Computer / e.soft Workstation has the following similarities to the product which previously received 510(k) clearance:

- have the same indicated use,
- use the same operating principle,
- incorporate the same basic product design

In summary, the E.CAM Computer described in this submission is, in our opinion, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2002

Mr. Richard S. Demke
Manager, Regulatory Affairs
Siemens Medical Solutions USA, Inc.
2501 North Barrington Road
HOFFMAN ESTATES IL 60195-5203

Re: K023190
Trade/Device Name: E.CAM Computer/e.soft Workstation
Emission Tomography System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving
and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 26, 2002
Received: September 25, 2002

Dear Mr. Demke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known) K023190

Device Name: E.CAM Computer / e.soft Workstation, Emission Tomography System (Computer)

Indications For Use: E.CAM Computer / e.soft Workstation is a Gamma Camera computer for nuclear medicine used to detect or image the distribution of radionuclides in the body or organ, using the following techniques:

- Planar Imaging
- Whole body imaging
- Tomographic imaging (SPECT) for non positron emitter
- Positron imaging by coincidence
- Positron imaging without coincidence up to 588 keV
- Display and process nuclear medicine, PET and CT images

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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